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Nos. 80-2182 and 81-11

IN THE

Supreme Court of the United States

OCTOBER TERM, 1981

INWOOD LABORATORIES, INC., *et al.*,
Petitioners,

v.

IVES LABORATORIES, INC.,
Respondent.

DARBY DRUG CO., INC., *et al.*,
Petitioners,

v.

IVES LABORATORIES, INC.,
Respondent.

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT

BRIEF FOR THE RESPONDENT

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Questions Presented

1. Was the Court of Appeals correct in holding the defendants liable for contributory infringement under §32 of the Lanham Act, 15 U.S.C. §1114, and basing said liability on the fact that (a) defendants sold their prescription drug in capsules that intentionally copied the appearance of the capsules in which plaintiff's CYCLOSPASMOL brand of the drug cyclandelate had long been sold; (b) defendants' look-alike capsules were illegally substituted in prescriptions calling for the dispensing of plaintiff's drug product and otherwise passed off by pharmacists as plaintiff's CYCLOSPASMOL cyclandelate; (c) the acts of the pharmacists were reasonably foreseeable by defendants; and (d) the copying of the capsule colors made the illegal substitution and passing off more likely to occur and more difficult for patients to detect?

2. Does an injunction permitting the sale of a drug product but restricting the copying of the appearance of the capsules in which a prescription drug has been sold, which supports the federal policy of preventing unfair competition and infringement as embodied in the Lanham Act, violate in any way the federal policy of encouraging competition by allowing the copying of the subject matter claimed in patents after their expiration, or any state policy encouraging the availability of generic drugs?

Statement Pursuant to Supreme Court Rule 28.1

Respondent Ives Laboratories, Inc. is a subsidiary of American Home Products Corporation, which also has numerous other subsidiaries.

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ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT

BRIEF FOR THE RESPONDENT

Statement of the Case

Defendants/petitioners sell a prescription drug known by the generic name cyclandelate in capsules identically copying the appearance of the distinctive blue and blue/red capsules in which plaintiff has long sold its CYCLO-SPASMOL brand of cyclandelate. Plaintiff/respondent does not dispute defendants' right to sell the drug, nor their right accurately to compare their product to plaintiff's. Plaintiff has, however, claimed that, by selling their cyclandelate in look-alike capsules, defendants (1) violate §43a of

the Lanham Act, 15 U.S.C. §1125(a), (2) are liable under New York law for unfair competition, and (3) are liable as contributory trademark infringers when pharmacists pass off the look-alike capsules as plaintiff's CYCLOSPASMOL brand of cyclandelate in violation of 15 U.S.C. §1114.

I.

The Proceedings Prior to Trial

The case was before the District Court and the Court of Appeals twice.[1] On plaintiff's Motion for Preliminary Injunction, the District Court assumed that an injunction against copying the colors of the capsules could never be granted. It held that (1) relief was precluded under federal and state law by the Supreme Court decisions in *Sears/Compco*[2]; (2) the appearance of capsules was not protectable as trade dress because the capsules were ingested; and (3) defendants could be liable for contributory infringement only if it were proved that they were accessories to the crime of illegal substitution or had conspired with the pharmacies or otherwise actively instigated or participated in their passing off. (PA 13a, 21a, 25a)

The Court of Appeals affirmed the denial of preliminary relief, but found "the case more difficult than did the district judge". (PA 30a) It unequivocally held, in a unanimous opinion written by Judge Friendly, that an injunction against the copying of the colors of a prescription drug capsule is available in certain circumstances.

On the contributory infringement claim, it characterized as the most serious wrongdoing the illegal substitution of generic cyclandelate in filling prescriptions for

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[1] The four decisions are printed in the Appendix to the Petition for Writ of Certiorari in No. 80-2182 and will be referred to as PA. The Joint Appendix is referred to as A. The trial transcript is TR.

[2] *Sears, Roebuck & Co.* v. *Stiffel Co.*, 376 U.S. 225 (1964); *Compco Corp.* v. *Day-Brite Lighting, Inc.*, 376 U.S. 234 (1964).

CYCLOSPASMOL, and mislabelling the generic as CYCLOSPASMOL. "Intermediate" wrongdoing includes legally substituting the generic, but then mislabelling it as CYCLOSPASMOL, or giving it no name at all. (PA 34a) In order to find the defendants liable for these acts of infringement, it was not necessary to prove that they were "accessories to the crime" of illegal substitution or that they actively participated in the retailers' infringement. They would be liable, the Court held, if they suggested, even if only by implication, that generic capsules be labelled with Ives' trademark, or continued to sell capsules facilitating passing off to druggists whom they knew or had reason to know engaged in such practices. (PA 35a) Citing *Coca-Cola Co.* v. *Snow Crest Beverages, Inc.*, 64 F.Supp. 980 (D.Mass. 1946) aff'd 162 F.2d 280 (1 Cir. 1947), *cert. denied*, 332 U.S. 809 (1947), it found that the "proper criteria" for liability were whether a reasonable person would realize he had created a temptation or opportunity for wrong for "l'homme sensuel" or that he was dealing with customers he knew would be peculiarly likely to use the product wrongfully. (PA 35a)

As to the 43a claim, the Court held that there is liability for copying the colors if they are not functional, and if they had acquired secondary meaning, i.e., that consumers associate the blue and blue/red capsule colors with CYCLOSPASMOL. (PA 48a, 50a) "The argument that, like functional elements, color ought to be automatically denied protection because of the risk of creating monopolies through tying up all available colors does not seem persuasive". (PA 50a) The Court also held that, given the method of sale, Ives had no way of identifying CYCLOSPASMOL to the ultimate purchaser other than by color, and that the capsule colors may constitute trade dress, although ultimately ingested. (PA 51a) It also acknowledged that "the blue and blue/red coatings of Ives' capsules do not contribute to their efficacy; any other colors would do as well . . . the case for functionality thus depends on the evidence proffered *by defendants* . . .". (PA 49a-50a, emphasis supplied)

The Court left open the question of how New York law would strike the balance between the state unfair competition claims and the policy of the generic drug law facilitating authorized substitution. (PA 52a)

A trial to the same District Court judge who denied the preliminary injunction was then held, in which substantial additional evidence on each issue was presented.

II.

Statement of Facts

A. *The Products of Ives and the Defendants*

The plaintiff Ives Laboratories, Inc. ("Ives") is what may be called an innovator company that introduces new drugs, does the extensive research and testing necessary to obtain approval of the Food and Drug Administration for their sale, and develops market acceptance of the products. (81A, 121A) The drug at issue is a vasodilator known by the trademark CYCLOSPASMOL and the generic name cyclandelate. This product, which is sold only by prescription, is used to treat vascular diseases, many of which are associated with aging. Cyclandelate therapy is generally long term. (81A, 94A)

When Ives began selling its cyclandelate, the chemical structure of the drug's active ingredient was patented. (TR 41-2a, 572A) The patent, which issued in 1955, expired in 1972, and Ives does not dispute that others are free to produce and market the drug.

Since 1962, Ives has sold its cyclandelate, in a 200 mg. dosage form, in a vivid blue capsule. (81A) Three years after expiration of the patent, it began to sell an additional dosage, 400 mg., in a blue/red capsule.[3] (81-2A)

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[3] The Ives cyclandelate is also sold in a 100 mg. pale orange tablet, but that has not been copied and is not therefore in issue except insofar as it demonstrates that cyclandelate may be sold in a form other than capsules. (84A)

Although there are many products in the vasodilator category other than cyclandelate, none are sold in capsules similar in color to those used by Ives. (95A, 104A) The colors were arbitrary when selected, were not mentioned in the patent, and are not dictated by the appearance of the drug, which is a white powder. (82-3A) The colors, and the trademark CYCLOSPASMOL, were selected to identify the product as Ives' product. (82A)

Ives has made extensive sales, exceeding $106,000,000, and done considerable promotion of CYCLOSPASMOL cyclandelate. (92-3A) To develop its professional acceptance, medical sales representatives have continually visited physicians, hospitals and pharmacies, and there have been print advertisements and direct mailings to professionals. (86A, 100-101A) File cards describing the therapy and indicating the colors of CYCLOSPASMOL have been left with physicians for use and reference, and the product is shown in color in the Physicians' Desk Reference, ("PDR") a widely used reference tool. (90A, Pl. Ex. 15) Although prescription drugs are not advertised to patients, they have had access to information about the Ives' product. In addition to the PDR, a Consumer Guide publication for laymen has described cyclandelate and noted that CYCLOSPASMOL is Ives' trademark and that the Ives' product is sold in blue and blue/red capsules. TR 80a, 82a, Pl. Ex. 19b) Further exposure has occurred through starter samples which physicians give to their patients, in which the blue and blue/red capsules are in bottles labelled to show Ives as their source, along with the Ives' trademark "CYCLOSPASMOL®" and the generic name cyclandelate. (Pl. Exs. 7, 8, 91A) All CYCLOSPASMOL capsules are imprinted with the name Ives and a National Drug Code identification number. (82A)

The defendants are manufacturers or distributors of generic drugs which, in this and other instances, not only copy ...e active ingredient after expiration of an in-

novator's patent (a right which Ives does not challenge),[4] but also intentionally copy the appearance of the capsules or tablets in which the innovator's product has been sold and, in some instances, even its cartons.[5] In this case, the capsule colors were copied identically and every attempt was made to conceal the true source of the defendants' product. Prior to the suit, the capsules bore no marking whatsoever, and defendants, after examining the capsules, could not even identify their own products.[6] (388A, 410a, 427a) Sherry Pharmaceutical Co., Inc. ("Sherry") not only copied the capsule colors, but also used the trademark SPASMOL, until this infringement was enjoined. (PA 59a) In promotional materials, defendants have emphasized the similarity of the colors and juxtaposed listings of their products with listings of the brands of various pioneer drugs, including CYCLOSPASMOL. (TR 107-8B, 586A-650A)

B. *Passing Off and Illegal Substitution*

Prescription drugs are commonly purchased in bulk and dispensed by pharmacists who remove tablets or capsules from the manufacturers' bottles (which, in the case of cyclandelate, contain 100, 500 or 1000 capsules) and transfer them, in the smaller quantities called for in the prescription, to a pharmacy vial bearing the pharmacy's own label. (TR 26a) The pharmacist is thus an integral part of the system for distributing drugs and for identifying them to

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[4] In some instances, they copy the product and its trade dress even before expiration of the patent. See, e.g., *SK&F, Co.* v. *Premo Pharmaceutical Laboratories, Inc.*, 625 F.2d 1055 (3 Cir. 1980) (hereafter referred to as *SK&F* v. *Premo*) and *Hoffman LaRoche, Inc.* v. *Premo Pharmaceutical Laboratories, Inc.*, 210 U.S.P.Q. 374 (D.N.J. 1980) (hereafter referred to as *Hoffman LaRoche* v. *Premo*).

[5] *E.R. Squibb & Sons, Inc.* v. *Premo Pharmaceutical Laboratories, Inc.*, 195 U.S.P.Q. 545 (S.D.N.Y. 1977).

[6] Premo, during the litigation, began imprinting the name Premo on the capsules. Inwood began imprinting the code number "258." (38A)

the consumer. It is the pharmacist who puts the name and label on the drug dispensed to the patient. A prescribing physician rarely sees what drug has been dispensed, or what it has been called. (256A, 259-60A, 214A)

Historically there have been numerous cases in which pharmacists have dispensed look-alike products instead of the branded products called for in prescriptions, and identified them with the innovator's trademark, with the apparent aim of increasing their own profits.[7] The practice was certainly known prior to passage of generic substitution laws in the 1970's. A 1979 Staff Report to the Federal Trade Commission on Drug Product Selection acknowledges that, after World War II, "some manufacturers went beyond merely encouraging pharmacists to dispense their version of a prescribed drug, and clandestinely began to manufacture 'counterfeit' drugs: products similar in size, shape and sometimes packaging to the popular brand-name drug . . . counterfeiting reached 'epidemic' proportions in the early 1950's". (FTC Report p. 144) As many as 25% of all pharmacists practiced substitution, which was then illegal, with surveys on individual products showing rates of illegal substitution as high as 40% (FTC Report p. 144).

The practice of illegal substitution and mislabelling has continued after passage of generic substitution laws.[8] In-

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[7] These include *Winthrop Chemical Co., Inc.* v. *Weinberg*, 60 F.2d 461 (3 Cir. 1932); *Smith Kline & French Laboratories* v. *Broder*, 125 U.S.P.Q. 299 (S.D. Texas 1959); *Smith Kline & French Laboratories* v. *Heart Pharmaceutical Corp.*, 90 F.Supp. 976 (S.D.N.Y. 1950); *Ross Whitney Corp.* v. *Smith Kline & French Laboratories*, 207 F.2d 190 (9 Cir. 1953) and *Pinoleum Co.* v. *Baron*, 121 Misc. 384, 201 N.Y.Supp. 44 (Sup. Ct. Kings County 1923).

[8] See, for example, *Merrell-National Laboratories, Inc.* v. *Zenith Laboratories, Inc.*, 194 U.S.P.Q. 157 (D.N.J. 1977); aff'd on procedural grounds, 579 F.2d 786 (3 Cir. 1978); *Hoffman LaRoche* v. *Premo, supra*, p. 6 n.4; *A.H. Robins Co.* v. *Medicine Chest Corp., et al.* (including Inwood Laboratories, Inc.), 206 U.S.P.Q. 1015 (E.D. Mo. 1980) (hereafter referred to as *A.H. Robins* v. *Medicine Chest*); *SK&F* v. *Premo, supra*, p. 6 n.4; *Pennwalt Corp.* v. *Zenith Laboratories, Inc.*, 472 F.Supp. 413 (E.D. Mich. 1979); *Boehringer*

deed, the increased availability of generic substitutes since passage of those laws and the recent expiration of many patents, as pointed out in the Government's Brief Amicus (p. 4, n. 12), may make the problem even more acute now. Defendants Premo Pharmaceutical Laboratories, Inc. ("Premo") and Inwood Laboratories, Inc. ("Inwood") have been parties to other suits in which such practices were involved. Premo has itself sued another manufacturer for selling a prescription drug similar in appearance to Premo's, alleging that, by so doing, that manufacturer would "facilitate, aid and abet in passing off defendant's product as Premo's, thus illegally putting an instrumentality of fraud in the hands of retail pharmacists", *Premo Pharmaceutical Laboratories, Inc.* v. *Zenith Laboratories, Inc.* (D.N.J. Civil Action No. 81-3816, Complaint ¶14).

Inwood's Vice President testified that he knew of the practice of illegal substitution and the defendants admitted that the duplication of the appearance of the innovator product makes such illegal substitution easier. (415A, 405-6A, 438a) Premo's President acknowledged that "it is obvious if a man is going to do something illegal like pass off counterfeit money it's easier if he has a good imitation". (405-6A) A distributor admitted that another of defendants' practices, namely providing listings of brands available from the market leaders juxtaposed with the lists of their look-alike products, also makes it easier for the pharmacist "with larceny in his heart". (228-9a)

Ives proved that in thirteen cases look-alike cyclandelate capsules had been illegally substituted for CYCLOSPASMOL cyclandelate and had been identified on pharmacy labels as CYCLOSPASMOL.[9] (36A, TR 248, 732-81A) In

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Ingelheim G.m.b.H. v. *Pharmadyne Laboratories, Inc.*, 211 U.S. P.Q. 1163 (D.N.J 1981) (hereafter referred to as *Boehringer* v. *Pharmadyne*).

[9] Contrary to the assertion of petitioner Sherry, there was not a "nationwide" shopping, nor were the pharmacists known "bad actors". Some Ives' employees selected pharmacies in various areas

addition, it showed that one pharmacist, packaging cyclandelate for sale to nursing homes, put the look-alike capsules into single dosage unit packs individually labelled CYCLOSPASMOL or CYCLANDELATE CYCLOSPAZMOL (sic). (104-5A, 576A) Subsequent to trial, six indictments were handed down in the Metropolitan New York City area alleging illegal substitution and mislabelling of generic cyclandelate in filling prescriptions for CYCLOSPASMOL. The Court of Appeals, while not assuming guilt of the parties, took judicial notice of these indictments. (PA 84a).

Ives also introduced a statistically projectible survey to show what Judge Friendly had called "intermediate" cases of wrongdoing, namely when substitution is made legally, but the look-alike is then passed off as Ives' CYCLOSPASMOL cyclandelate. This survey, which was conducted in what the Court of Appeals characterized as a "rigorous and impartial manner", showed that 29% of the legally substituted look-alikes were mislabelled by pharmacists as CYCLOSPASMOL.[10] (TR 80-87, Pl. Ex. 82, 354-61A) In addition, in nine of seventeen instances where prescription bottles were produced by patients during survey interviews (infra p. 16), the look-alike capsules were erroneously identified on pharmacy labels as CYCLOSPASMOL. (TR 109-10a, 66-70B, 78-9B, 577-585A) This occurred de-

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of the country which they thought might be making illegal substitutions and prescriptions were presented to determine whether this was so. (36-37A) Inwood now claims for the first time that the substitutions in Michigan were not illegal. They were. The prescriptions were written for CYCLOSPASMOL. Under the law then in effect, even without the direction "dispense as written", it was unlawful to dispense a substitute without first orally advising the consumer. Michigan Public Health Code, §17755(1). Affidavits submitted on the motion for preliminary injunction by witnesses then deposed by defendants, confirm that the required disclosures were not made.

[10] This figure of 29% is correct, not the 12% referred to in the dissent. In computing how many pharmacies mislabel generic cyclandelate as CYCLOSPASMOL, the only true measure is to look to pharmacies that dispensed the generic. Those that did not carry the generic and thus did not substitute at all were properly omitted in computing the percentage of mislabelling.

spite the fact, acknowledged by defendants' expert on pharmacy practice, that pharmacists know the difference between the generic name and the trademark for a drug product. (271A) All manufacturers' bottles from which pharmacists dispense prominently show the generic name. (TR 25a, Pl. Ex. 5, 6, TR 106-7B, Pl. Ex. 39-45)

Thus, thirty-four labels on prescription vials or unit dose packs containing defendants' look-alike cyclandelate showed Ives' trademark CYCLOSPASMOL. Twenty-one showed only CYCLOSPASMOL or the trademark with the generic name, e.g., CYCLOSPASMOL (cyclandelate). (TR 109-112a, 114a, 66B, 70B, 247-248, 392-3, 377; 577-9A, 581-4A, 732A, 736A, 748A, 752A, 756A, 760A, 764A, 770A, 774A, 778A, 781A, 719A, 726A, 723A) On others the trademark was shown with some other designation, as, for example, "CYCLOSPASMOL 400 Cooper", "Rugby CYCLOSPASMOL", or "CYCLOSPASMOL (G)". (TR 247-9, 78B, 82B, 740A, 585A, 576A) Six labels showed "Generic CYCLOSPASMOL" or a variation such as "CYCLOSPASMOL Gen." (TR 392-3, 377; 576A, 699A, 695A, 691A, 703A, 707A) In the New York State shop, in six instances where the generic was dispensed and not labelled with Ives' trademark, the pharmacy label showed no manufacturers' name or other indication of source and, in a Premo shopping, fourteen of twenty-five pharmacists failed to put the manufacturer's or distributor's name on the labels, leaving the capsule color as the only effective indication of source. (Pl. Ex. 82, TR 85, 376A) When, in the Ives' survey, the pharmacist disclosed that a generic had been dispensed, this occurred because the shopper, as part of the survey, was required to ask, after the medication was dispensed, whether it was in fact a generic, and to then record the answer. (TR 81, Pl. Ex. 85)

An examination of prices charged shows a substantial difference from pharmacy to pharmacy. In the New York State survey, for example, the price for the CYCLOSPASMOL 400 mg. dosage ranged from 8.7 to 22.6 cents per capsule. (Pl. Ex. 82G, 820O) Although this practice

was not uniform, there were some substantial windfalls for pharmacists dispensing the generic look-alikes. One pharmacist mislabelling the blue 200 mg. look-alike as CYCLOSPASMOL charged a higher per capsule price than all but one of twenty-three pharmacists who had dispensed the true CYCLOSPASMOL. (TR 392-3, Pl. Ex. 82T, 82Y) One of the pharmacists dispensing the 400 mg. capsules, mislabelled as CYCLOSPASMOL, charged a higher price per capsule than all but two of the 25 pharmacists dispensing 400 mg. CYCLOSPASMOL. (TR 377, Pl. Ex. 82HHH, 82PPP, 82ZZZ) In the Premo shopping, two pharmacies charged more for dispensing cyclandelate than for CYCLOSPASMOL. (379-82A) Once when the look-alike was mislabelled as CYCLOSPASMOL, the "saving" passed on to the consumer was only 55 cents, despite the fact that a 1977 Sherry catalog shows that the pharmacist's own saving on a bottle of 100 cyclandelate capsules, as compared to a comparable bottle of CYCLOSPASMOL, was $6.55. (380A, 624-5A)

A March 13, 1979 Report of Attorney General Robert Abrams and Consumer Affairs Commissioner Bruce Ratner on the New York Generic Drug Substitution Law confirmed that nearly one quarter of the pharmacies in New York violate the generic drug law when filling prescriptions and that they are not passing along the full dollar savings to consumers. The report also verifies that the retail price charged by some pharmacies for the generic substitute is often significantly higher than the retail price charged by other pharmacists for the branded product. And, the Report concludes, the State Pharmacy Board has given prosecution of violations of the New York generic drug law a low priority. (TR 933, 368-74A)

C. *The Functionality Issue*

When chosen by Ives, the blue and blue/red colors were completely arbitrary. They do not contribute to the therapy offered by cyclandelate, which is a white powder, and they are not medically necessary. Many thousands of other color

combinations could have been selected by defendants for the capsules, and they could even have chosen to sell the drug in tablet form. (TR 24a, Pl. Ex. 3) One competitor, W.E. Hauck, Inc., has sold cyclandelate in an all red 200 mg. capsule for at least two years. (124-5A, Pl. Ex. 19, 729A) Its product is shown on the Georgia Medical Assistance Drug List and in the Consumer Guide publication on prescription drugs as a generic cyclandelate available to patients. (TR 80a, 82a, 15, 573-5A, 730A)

Other manufacturers do not feel similarly compelled to copy the innovator. Information in the Physicians Desk Reference alone shows that, in numerous instances, the same drugs in the same dosage forms, but in different colors, are available and color change will occur in medications for both acute and long term therapy and even for treating anxiety (169-71A, 185-6A, 109A, 110-11A, Pl. Ex. 131-135). For example, the most widely prescribed vasodilator, papaverine hydrochloride, comes from different sources in the same dosage but in seven completely different color combinations. (TR 937-939, Pl. Ex. 131) No proof was offered that patients would not equally accept other color choices for capsules containing cyclandelate.[11]

Several expert witnesses testified. Dr. Heinz Lehmann, one of the world's foremost psychiatrists, and a member of the Research Advisory Committee to the New York State Department of Mental Health, who has treated over 10,000 patients, testified that it is not medically necessary for the same dosage form of the same prescription drug to be of the same color. He had treated patients whose drug colors were changed and encountered no refusals to take the medication, no anxiety reaction on the part of the patients, and no indication that the therapeutic effect was diminished by the color change. (191-4A) Dr. Eric

[11] Defendants' Dr. Stempel testified that look-alike generics had been marketed for years, and provided a chart of look-alikes, but he did not know whether any of them were presently marketed. Twenty-eight were round white or off-white tablets. Several were the subject of pending litigation. Thirty-seven were also available in non-look-alike forms. (265-6A, 304A)

Fine of the Albert Einstein Medical Center in Philadelphia, and Dr. Vincent Desiderio, Medical Director of the Sidney Hillman Medical Center, related similar experiences. (109-13A, 311-14A,) All three physicians testifying for defendants also acknowledged that generics which did not copy the appearance of innovator drugs were available, and that their patients had from time to time received medication in colors different from those previously dispensed without unfavorable reaction. (219A, 299-301A, 257-8A) One of defendants' witnesses, Dr. Taylor, admitted that her personal view that all drugs with the same ingredient should be the same color was not a reflection of what actually exists in the market place. (219A) All three of defendants' physicians testified that, where their patients inquired about color change, it was explained to the patient's satisfaction, except for one patient with cardiac problems and a few with Parkinson's disease who did not want to switch the source of their medication. (255-8A, 296A, 299-301A, 250A, 255A, 210A) The total of six physicians who testified about their experience with color change represented collectively over 125 years of medical practice, and had treated tens of thousands of patients, yet these are the only examples of patient refusal any could remember.

Reliance on color as an identification of a kind of medication can be dangerous. The practice of commingling medication in one container, and selecting from that collection by color, was universally condemned particularly since a single patient could be taking medications which are different, but which come in capsules or tablets of a very nearly identical appearance. (115A, 231-2A, 253A, 261A) Defendants' Dr. Bloom acknowledged that a patient relying on color to select one type of medication over another in those circumstances could be in trouble. 261A) The safest and most sure way of identification for professionals is a drug's National Drug Code identifying number, not its color. A specialist in emergency medicine testified that a responsible physician would not at-

tempt to make a positive identification of an overdosed drug by color alone and that such reliance could be disastrously harmful. (196-7A) The Drug Abuse Manual for Law Enforcement Officers, which notes that some over-the-counter products may look like amphetamines or barbituates, counsels that "simple visual inspection cannot be relied upon for drug identification". (197A, Pl. Ex. 114) Defendants' witness Dr. Stempel, a pharmacy expert, confirmed the dangers in relying on color (TR 807, 365A):

> "Any attempt to identify a drug wholly by its physical characteristics, aside from being time-consuming, can be hazardous, and this procedure should be discouraged . . . even though one life may be saved by identification by appearance, encouraging such a procedure may lead to other lives being lost."

Uncontradicted evidence as to pharmacy practice was submitted. Pharmacists, including the President of the Pharmaceutical Society of the State of New York, testified that the same drugs in the same dosage form but in different colors are and have been widely available and used, and that they had not encountered patient refusal of a drug because of a color change. (170-2A, 183-8A) The Nassau County Medical Center has often changed the supplier of its drugs, and thus their color, and encountered no resistance to color change from patients, doctors, or nurses. (187-8A) If a change in color results in a patient inquiry, an explanation by the pharmacist or physician is sufficient and there is no evidence that professionally responsible physicians or pharmacists would be unwilling to take the time to explain the change. (172A, 188A) Defendants' pharmacist witnesses likewise acknowledged that color change has occurred in their practice, and that they stock generics in colors different from the market leader. (276A, 242-6A)

The entire testimony about industry resistance to non-look-alikes was as follows. A pharmacist testified that he

preferred not to purchase cyclandelates in green capsules, a color once offered by an affiliate of Inwood. However, his reason was concern about a problem he had when, because of a color change, two *entirely different* medications looked similar. (276-7A, 280-1A) An officer of Inwood testified that someone told him that one or two hospitals complained about the product sold in green capsules, but he could not identify them or furnish details about the complaint. (418A, Pl. Ex. 144 pp. 85-6) Finally, a wholesaler testified that he preferred to sell look-alikes. He was an employee of a defendant in a case then pending in which such practices were challenged, and subsequently enjoined. (TR 669, *A.H. Robins* v. *Medicine Chest*, supra p. 7 n.8)

Additional uncontradicted and significant testimony related to the actual purchasing practices of hospitals and similar institutions including the New York City Health and Hospitals Corporation, the Nassau County Medical Center, the Sidney Hillman Medical Center and others. Without exception, purchasing decisions at such institutions are *required* to be made on price, not color. (184A, 215A, 241-3A, 301-2A) Such institutions frequently change their source of supply and, in many instances, this results in a color change. (183-6A, 243A, 283A) Local, state and federal bidding specifications for cyclandelate throughout the country, including those of the Veterans' Administration, include no reference to color.[12] (315-17A)

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[12] The only exception is New Jersey's bidding form for 200 mg. cyclandelate which refers to the color blue. It does not, contrary to the statement in Inwood's brief, have a color requirement for the 400 mg. dosage form. Since New Jersey purchases other products regardless of color, it is probable that the State would also remove that requirement were a bid received for 200 mg. cyclandelate sold in capsules other than blue. There was no evidence proffered by defendants that they ever attempted to make such a bid (316A, 318A)

D. *Confusion and the Significance of Color*

Ives also introduced a survey in support of its claim that duplication of the capsule colors causes confusion, since the colors are associated with CYCLOSPASMOL. There was extensive testimony about the procedures used to design, execute, and validate the results of this survey.[13] (131-4A, 151-3A, 158-9A, 165-7A, TR 69, 77, 319A, 347A, 352A) Seventy-one patients were interviewed (not thirty-six as stated by the District Court), forty-three in an initial survey, and twenty-eight in a replication survey. (319A, 347A, 352A) Three pharmacy bottles containing defendants' look-alike capsules were displayed to each patient. The bottles were all correctly labelled with the name of the manufacturer or distributor, and the generic name of the product, cyclandelate. Premo's capsules bore the imprint Premo. (141A, Pl. Ex. 80a-c) Nonetheless, the combined misidentification by patients of look-alike blue and blue/red capsules as CYCLOSPASMOL in the original survey was 70%, with 40% making a spontaneous misidentification.[14] (TR 69, 319A, 323A, 347A, 350A) Were one to discount patients who were not even aware that CYCLOSPASMOL had ever been prescribed for them, the total misidentification increased to 97%, with 57% making a spontaneous misidentification. The replication patient survey showed similar results. (TR 77, 352A) 79% of the patients in the original survey said they used color to make their identification of what they erroneously believed to be CYCLOSPASMOL. (TR 72, 319A, 325A, 347A)

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[13] The District Court made no findings on the methodology or survey techniques used, but gave the survey little weight. The Court of Appeals decision does not mention the survey. It will not be extensively discussed here since it relates principally to Ives' 43a claim, which, not having been decided below, is technically not before this Court.

[14] A spontaneous misidentification is one in which the person interviewed identified the look-alike capsules as CYCLOSPASMOL upon seeing the capsules, without first having been shown a list of ten drug names.

III.

The Decisions After Trial

The District Court again rejected plaintiff's claims. On the contributory infringement claim, it apparently did not believe that furnishing the look-alike capsules could itself result in liability. Rather it looked only at defendants' promotional material and believed that it could not "fairly be read as suggesting to druggists that they affix Ives' mark to bottles containing defendant's capsules". (PA 59a) It also speculated that the pharmacists who mislabelled the look-alikes as CYCLOSPASMOL (none of whom were deposed or called by defendants as witnesses) must have misunderstood the requirements of the New York Drug Substitution Law. (PA 60a) The Court considered requiring defendants to affix labels on bottles sold to pharmacies warning against illegal substitution or misbranding, or requiring defendants to imprint some identification on their capsules, but rejected both forms of relief as ineffective. (PA 61a) It thus gave no relief at all.

As to the claim under §43a, it held that the colors of the capsules were functional. (PA 63a) In so doing, it did not explain why cyclandelate differed from the numerous generic drugs sold in non-look-alike forms. It also held that Ives had failed to prove secondary meaning, despite evidence of extensive sales and promotion. Although patients in a survey had identified the defendants' look-alike capsules as CYCLOSPASMOL, the Court held that plaintiff had not also proved that they thought CYCLOSPASMOL was a trademark. Indeed, it found without benefit of testimony from a single patient, or other evidence, that to them the word refers to an ingredient. (PA 67a)

The Court assumed that relief under state law was not precluded by *Sears/Compco*, but held that the "interest of the patients must be weighed against the policy expressed in the New York Education Law to encourage legal sub-

stitution of lower priced drugs". (PA 69a). Although a change in capsule color might deter a wrongdoer, the Court believed it would also inhibit legal substitution, and denied relief under this cause of action as well. (PA 69a)

The Court of Appeals reversed the decision of the District Court. Although it did not decide the §43a or state unfair competition claims, it did specifically reject the holding that the colors were functional, stating that defendants "have not offered any persuasive evidence of a legitimate reason unrelated to CYCLOSPASMOL for using identically-colored, look-alike cyclandelate capsules instead of capsules of a different color, size or shape, which would minimize the practice of mislabelling, illegal substitution or confusion". (PA 84a) It specifically found "unconvincing" the assertions that capsule colors are functional and should be copied because the look-alikes reduce patient confusion or anxiety, enable doctors to communicate with patients more easily concerning their medication, and aid in identification in emergencies. (PA 84-85a) The Court also emphasized that there was no evidence that patients would be confused by receiving a non-look-alike, or that a color change could not easily be explained. (PA 85a)

On the contributory infringement claim, which is the subject of this appeal, the Court held that, by furnishing the look-alike capsules, defendants were liable when pharmacists misidentified them with plaintiff's trademark on pharmacy vials containing those look-alike capsules. It acknowledged that "it was surprising that Ives was able to produce as many instances" of illegal substitution as it did, and that Ives' pharmacy shop, done in a "rigorous, impartial manner", disclosed substantial evidence of intermediate cases of contributory infringement, i.e., mislabelling of legally substituted look-alikes. (PA 81a) This evidence, the Court held, was clearly sufficient to establish a violation of §32 of the Lanham Act, since the manufacturers could reasonably anticipate that their look-alike product would be substituted illegally or mislabelled by a substantial number

of druggists. (PA 82a) The fact that the capsules were look-alikes reduced the likelihood of detection by patients.

The Court also noted that the record did not justify the finding that the mislabelling occurred as a result of confusion by pharmacists, and that, in fact, it was the District Court judge himself who suggested this, in a casual exchange with one of the witnesses. (PA 83a)

The Court did suggest that listing the comparative prices of CYCLOSPASMOL and generic cyclandelate may have furnished an added inducement to pharmacists, when combined with the furnishing of look-alike capsules and catalogs describing their appearance. However, the relief given was an injunction against the sale of the blue and blue/red look-alikes; there were no restrictions suggested, and none imposed by the District Court on remand, on accurate price comparison or other truthful advertising of the defendants' product. (PA 102-4a)

Summary of Argument

Ives does not seek to prevent the sale of generic cyclandelate. It does not seek to restrict truthful comparative advertising by manufacturers of generic cyclandelate. It does ask this Court to affirm a decision imposing on the defendants the obligation to compete fairly and, specifically, not to sell their cyclandelate drug in capsules that imitate the appearance of the blue and blue/red capsules in which Ives' CYCLOSPASMOL brand of cyclandelate has long been sold.

The Court of Appeals correctly held that, by furnishing these look-alike capsules to pharmacists who illegally substituted and otherwise passed them off as Ives' CYCLOSPASMOL capsules, the defendants were liable for contributory infringement under §32 of the Lanham Act, 15 U.S.C. §1114. The acts of those pharmacists were clearly an infringement of the CYCLOSPASMOL trademark. Its validity was never challenged, and no evidence was ever

submitted that it functioned as anything but a trademark. To affix that mark to products emanating from a source other than Ives obviously violates §32.

To hold the defendants vicariously liable for that infringement by pharmacists is completely consistent with well-established principles of tort law holding persons liable for the reasonably foreseeable consequences of their actions. Pharmacists, as the direct link to the consumer, play an integral and unique role in the marketing of prescription drugs. It has historically been known that they do not always behave in a responsible, professional manner. When, in this and numerous other cases, they have been presented with prescription drugs mimicking the appearance of the innovator, and further tempted by the increased profits possible, pharmacists have illegally substituted or otherwise passed off the look-alikes for the branded products of the innovators. In this case, defendants admit that their duplication of the capsule colors made the pharmacists' acts of passing off more likely to occur, and less easy to detect.

Color duplication results in the deception of those patients who receive look-alikes when their physician has directed that only the branded product be dispensed. The similarity in appearance makes it unlikely that any patient would discover the ruse. The look-alikes also do a disservice to patients whose physicians have authorized generic substitution. Seeing the familiar colors, they will not be alerted to the fact that substitution has occurred, and will not know that they should require the pharmacist to pass along some saving to them.

To deny liability in these circumstances would represent an unwarranted and unwise departure from well-established law and, in particular, well-established case law setting standards applicable to the unique circumstances that exist in the marketing of prescription drug products. And, absent some compelling reason for allowing defendants to continue to provide the instrumentality of fraud to the

pharmacists, the Court was also completely correct in fashioning as the only effective relief an injunction against copying the appearance of Ives' capsules.

The defendants failed completely to furnish any legitimate reason for copying the appearance of the Ives' capsules let alone one so compelling as to justify the continued sale of a product that has been the instrument of fraud and deception of the consumer. In this as in other cases defendants have claimed that the colors are functional, and thus free for all to copy. Their argument rests on the premise that patients will refuse a color change, and that, by selling the look-alikes, they avoid that refusal by concealing the change.

Other manufacturers, however, sell drugs having the same therapeutic indication and ingredients as the market leader, but do not copy the appearance of the tablets or capsules in which that product has been sold. No legitimate reason was given why the defendants should not also follow that practice. The claim that a color change would lead to a decreased availability of generic drugs, or a rise in their cost, has never been supported by probative evidence. The Court correctly held, as have other Courts addressing the issue, that there was a failure of proof by defendants.

Requiring that cyclandelate be sold in capsules that do not copy the Ives' capsules is completely consistent with the policy, as embodied in the *Sears/Compco* cases, of allowing the copying of the subject matter of patents after expiration. Defendants are free to copy the *product*, i.e., cyclandelate, but not the trade dress in which the product has been sold by Ives.

To enjoin the copying of the blue and blue/red capsule colors is not, as the Department of Justice suggests, to err on the side of overdeterrence. The benefits to be gained by requiring a change in color are not marginal. They are extremely important. They include not only the interest of the plaintiff in assuring that the drug products

of others are not passed off as plaintiff's, but also the interest of the public in being able to determine that the correct drug has been dispensed, and the correct price charged. They assure that the patient is not deprived of the right to exercise informed consent as to the source of his or her medication. These interests far outweigh any cognizable interest the defendants may have in continuing their copying. There is no proof in this record that their ability to compete fairly in the sale of cyclandelate will be diminished were the colors changed.

ARGUMENT

I.

The Court of Appeals Was Correct in Holding That the Defendants, by Furnishing Cyclandelate in Capsules Imitating the Appearance of Ives' Cyclospasmol Capsules, Were Guilty of Contributory Infringement When Those Capsules Were Passed Off as Cyclospasmol.

A. *The Legal Criteria Applied Were Correct and Liability Was Factually Established*

We have, with prescription drugs, a unique marketing situation in which a third party, the pharmacist, not only plays an integral role, but, in fact, actually labels the merchandise as dispensed to the ultimate consumer. Respondent does not claim that all or most pharmacists cut corners, or attempt to deceive consumers and increase their profits by illegally dispensing or mislabelling the defendants' product. However, historically, such activity has been a serious problem for the innovator, and for the consuming public. In the 1950's, for example, the manufacture of look-alike drugs had reached epidemic proportions, and pharmacists were making illegal substitutions 25% of the time. (FTC Report, *supra*, p. 7) Evidence submitted in other recent cases shows that the practice continues (*supra*,

p. 7 n.8) Although difficult to discover, since patients do not realize there has been illegal substitution of a look-alike, and thus do not report it, Ives nonetheless showed numerous instances of illegal substitution of cyclandelate. It also showed that the product is passed off by pharmacists as CYCLOSPASMOL 29% of the time when the look-alike is legally dispensed. (*supra*, p. 9)

The widespread existence of passing off and illegal substitution over the years has spawned many law suits which establish and delineate the liability of those, such as the defendants herein, providing look-alike drugs.

In *William R. Warner & Company* v. *Eli Lilly & Company*, 265 U.S. 526 (1924), this Court acknowledged the vicarious liability of the manufacturer of a liquid quinine preparation, which was passed off as the product of the pioneer. It rejected the argument that liability does not lie because the manufacturer, at its point of sale, does not deceive its customers. The fact that those customers, the pharmacists, were not deceived, but "knew exactly what they were getting is of no consequence". (p. 530) The wrong, the Court held, "was in designedly enabling the dealers to palm off the preparation as that of the respondent". (p. 530) The question of liability in that case seems one which not even the defendants herein would challenge, since the manufacturers' salesmen had suggested to pharmacists that, without danger of detection, prescriptions and orders for the products of the market leader could be filled by substituting the copy. By also pointing out the enhanced profit to be made, they further actively induced the substitution which, at that time, was illegal.

The *Lilly* case was only a first step, and clearly does not set the far limits of liability. Subsequent decisions hold that a manufacturer cannot escape liability merely because it does not employ salesmen who actively induce or participate in the passing off. *Smith Kline & French Laboratories* v. *Heart Pharmaceutical Corp.*, *supra*, p. 7 n.7,

presents a typical marketing scheme which historically has triggered liability (90 F.Supp. at p. 978):

> "[T]he affidavits submitted do not allege any direct instance in which defendants or their agents suggested to druggists that their product might be substituted for that of plaintiff without danger of detection. However, this court cannot be insensible to the practical effect of defendants' advertisements and the use of the term 'Color Guaranteed'. Certainly the possibility of substitution was brought to the mind of druggists by the pictorial representation of the shape and the designation of the colors of defendants' tablets as well as the lower prices at which they could be obtained."

The Court in *Smith Kline & French Laboratories* v. *Broder, supra,* p. 7 n.7 also acknowledged the existence of illegal activities by pharmacists and held the manufacturers liable for contributing to them (125 U.S.P.Q. at p. 302):

> "Substitution by retail druggists of another drug, or the product of another manufacturer, than that called for by the physician's prescription, is an unethical practice in the drug business, and is criminal in this State [Texas], as well as many others. It is, however, practiced *in many instances,* there being a financial inducement thereto, in that the imitative drug usually sells for a fraction of the price which the genuine and well advertised product commands." (emphasis supplied)

The defendant in that case had duplicated the shapes and colors of the plaintiff's products, and emphasized these similarities in circulars distributed to retail pharmacists. The Court held that "the obvious purpose and effect of defendant's said advertising is to suggest that the druggist can readily substitute defendant's imitation drug products in filling physicians' prescriptions calling for plaintiff's trademarked products" and found the manufacturer liable.

These standards for holding the manufacturer liable have not been relaxed with the advent of generic substitution laws which provide that substitution, when authorized, is legal. It has been held, for example, that New York's generic drug substitution law "does not promote unfair competition or the infringement of drug patents and trademarks; nor does the Law create any defenses to such claims . . . plaintiffs' rights and remedies under the patent and trademark laws are the same now as they were prior to the passage of the law," *Pharmaceutical Manufacturers Association, et al.* v. *Whalen* (New York Court of Appeals, No. 650, December 22, 1981, Slip Op. p. 7). The problem of illegal substitution, and misbranding, is still very real. Its exact magnitude cannot be known because the acts complained of are clandestine, and not discovered by patients who cannot tell they have been deceived.

Although other recent cases were decided under §43a of the Lanham Act and various state laws of unfair competition, rather than §32 of the Lanham Act, they are nonetheless directly pertinent insofar as they recognize the unique distribution pattern and the resulting standard of accountability still applicable in the prescription drug industry. In *A. H. Robins* v. *Medicine Chest, supra,* p. 7 n.7, defendants were enjoined from selling a generic drug in look-alike blue tablets. The Court applied this general standard in finding Inwood and other defendants liable (206 U.S.P.Q. at p. 1019):

> "Anyone who puts goods into the hands of dealers for sale to the public which contain the means for deceiving purchasers, and/or which can be reasonably anticipated to so deceive, is subject to an injunction against the further provision of these means . . . Thus defendants . . . can be held liable for putting their products into various dealers' hands, such as defendant-pharmacists, *if they can reasonably anticipate that their goods may be passed off as goods of another, whether or not they conspired with the dealer or*

intend the substitution of the goods involved." (emphasis supplied)

Similarly, the Court of Appeals for the Third Circuit, in *SK&F* v. *Premo, supra,* p. 6 n.4, found that the defendant's conduct was actionable since it put a look-alike prescription drug capsule "in the hands of a pharmacist in a form in which the manufacturer can reasonably anticipate that it may be passed off as another product *even if the manufacturer does nothing else to encourage passing off.*" (625 F.2d at p. 1062, emphasis supplied) In *Boehringer* v. *Pharmadyne, supra,* p. 8 n.8, it was also held that, by copying plaintiff's orange colored tablets, the defendants "made possible the 'switching' of consumers for the profit of pharmacists," and indeed "provided the essential ingredient for that practice." (211 U.S.P.Q. at p. 1183) In *Hoffmann La Roche* v. *Premo, supra,* p. 6 n.4 liability was similarly determined on a realistic basis (210 U.S.P.Q. at p. 383):

> "When a manufacturer produces articles that copy the trade dress of another and puts them in the channels of trade, then though he sells only to wholesalers or distributors he cannot realistically be heard to say that he is unaware or ignorant of what retailers may do by way of 'passing off' or 'palming off' his goods as those of another."

The criteria applied in this long-established line of other prescription drug cases, and in this case, are but applications of the basic principle of tort law holding one liable for the reasonably foreseeable consequences of his or her actions. The concept is firmly established in our jurisprudence, specifically in other unfair competition cases, which hold that "it is unfair competition for a person to put a product into a dealer's hands which a producer can reasonably anticipate may be easily passed off as the goods of another," *Union Carbide Corp.* v. *Ever-Ready, Inc.,* 531 F.2d 366, 384 (7 Cir. 1976), *cert. denied,* 429 U.S.

830 (1976); *Corning Glass Works* v. *Jeannette Glass Co.*, 308 F.Supp. 1321, 1326-28 (S.D.N.Y. 1970), aff'd on opinion below, 432 F.2d 784 (2 Cir. 1970); *Andrew Jergens Co.* v. *Bonded Products Corp.*, 21 F.2d 419, 424 (2 Cir. 1927), *cert. denied*, 275 U.S. 572 (1928); and *Stewart Paint Mfg. Co.* v. *United Hardware Distributing Co.*, 253 F.2d 568, 575 (8 Cir. 1958); see also R. Callmann, The Law of Unfair Competition Trademarks and Monopolies, §87.2(b)(1) (3d ed. 1970). To absolve the defendants in this case would represent a severe inroad on this well-established body of law.

The contributory infringement concept is a salutary one. Ives did sue one druggist who had illegally substituted and misbranded look-alike cyclandelate capsules. He admitted liability and consented to an injunction. (29-31A) However, there are over 3,000 pharmacies in New York State alone. (TR 80) The purpose of the contributory infringement concept is both to avoid the multiplicity of suits resulting were one required to sue even a small proportion of those many retailers, and also to have the person providing the means for deception shoulder the responsibility. Where the issue is whether patients are receiving a prescription drug from the source specified by their physicians such relief is imperative.

The Government suggests that the Court should have applied a stricter rule of scienter and Inwood would require that Ives prove that it continued to sell to specific, identified pharmacies engaging in the acts complained of. These approaches are naive. The defendants did not accidentally select the colors blue and blue/red for their cyclandelate capsules. They selected them only because CYCLOSPASMOL capsules were blue and blue/red. The excuses they fashioned for copying were held to be "unconvincing" and "not persuasive." (PA 84) The defendants also knew that they were releasing into the stream of commerce an instrumentality for fostering deception. They have admitted that duplication of the capsule ap-

pearance makes illegal substitution and misbranding by the pharmacist more likely, and less easily detectable by the patient. Such misbehavior by pharmacists has unfortunately long been a known fact of life and defendants cannot plead ignorance of this practice in the drug trade. In fact Inwood admitted to knowing of the practice. Defendants have a special obligation not to contribute to this wrongdoing, particularly given the fact that the product involved is a prescription drug. Instead, they made it easier by providing look-alikes, and encouraged the wrongdoing further by noting the color identity in catalogs, and matching their products in columns with the trademarks of Ives and other innovators.[15]

This entire body of law establishing the liability of drug manufacturers is solidly based on the realities of the prescription drug business and conforms to established standards of accountability in tort law. It should not be disturbed except for the most compelling reasons, which clearly have not been shown on this record.

B. *There Was Direct Infringement by Pharmacists of the CYCLOSPASMOL Trademark*

Inwood argues that the Court erred in finding contributory infringement because it had not first specifically held that the direct wrongdoers, the pharmacists, had infringed Ives' trademark. Since those pharmacists applied Ives' CYCLOSPASMOL trademark to products that were not Ives' CYCLOSPASMOL cyclandelate, the argument must be characterized as specious.[16]

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[15] *Coca-Cola Co.* v. *Snow Crest Beverages, Inc.*, supra p. 3 is distinguishable. It is common knowledge that some physicians require that their patients receive exactly the branded drug prescribed; as aforesaid, the existence of the look-alikes interferes with that choice. The Court specifically noted, however, that there was no evidence in *Snow Crest* that customers wanting a cola drink made specific orders by brand name or that furnishing a substitute would interfere with their choice. (64 F. Supp. at p. 988).

[16] While less blatant an infringement, this is true even of those vials labelled CYCLOSPASMOL Gen, or CYCLOSPASMOL

It does, however, lead to another argument made by Inwood, and echoed by defendants' trade association, namely that CYCLOSPASMOL is not a trademark, but merely signifies the ingredients in the drug. This hypothesis was first interjected into this case by the District Court after trial when it held that "such patients as read their prescriptions do not attribute to Cyclospasmol 'any other meaning than as an ingredient in a general compound, to which faith and science might impart therapeutic virtue.' " (PA 67a) The quotation is not from any evidence in this case, but is, verbatim, a finding in a case involving a challenge to the trademark status of "aspirin." In that case there was substantial evidence that "aspirin" had been used descriptively even by the plaintiff, which promoted its product as "BAYER Tablets of Aspirin," and had thus become recognized as a generic name, *Bayer Co.* v. *United Drug Co.*, 272 Fed. 505, 510 (S.D.N.Y. 1921).

In the present case, however, defendants did not question the trademark status of CYCLOSPASMOL, and stipulated that it is a valid, subsisting, incontestable registered trademark. (34A) Ives is entitled to a statutory presumption of validity, and the District Court clearly erred in presuming invalidity of the trademark and its registration and suggesting that Ives had the burden to prove its trademark was a trademark, 15 U.S.C. § 1115a. Even had the defendants raised the issue of validity at trial and introduced evidence to support the claim, (which they did not) the cases clearly establish that defendants would have the burden to prove by "a rather clear and convincing showing" that CYCLOSPASMOL was *not* a trademark, *E. I. duPont de Nemours & Co.* v. *Yoshida International, Inc.*, 393 F.Supp. 502, 528 (E.D.N.Y. 1975); *McGregor-Doniger Inc.* v. *Drizzle, Inc.*, 599 F.2d 1126, 1132 (2 Cir.

Generic. As the Court pointed out in *Boehringer* v. *Pharmadyne, supra*, p. 8 n.8, "whether adding the letters 'gen' or the word 'generic' actually tells the consumer that he or she is being switched from Persantine is questionable . . . Consumers are unlikely to learn of the change in medication from what is probably, for them, an obscure word or phrase." (211 U.S.P.Q. at p. 1181.)

1979); *Marks* v. *Polaroid Corp.*, 129 F.Supp. 243 (D. Mass. 1955) aff'd 237 F.2d 428 (1 Cir. 1956), *cert. denied*, 352 U.S. 1005 (1957).

It has also been suggested, again belatedly, that, when the patent on the active ingredient in cyclandelate expired, competitors were free not only to make the product, but also to use the CYCLOSPASMOL trademark. There is, however, no rule of law that its trademark follows a product into the public domain upon patent expiration. There is not even a presumption that the name becomes *publici juris*, Handler and Pickett, Trade-Marks and Trade Names —An Analysis and Synthesis: I, 30 Columbia Law Review 168, 187 (1930). In each case, facts establishing the genericness of the one-time trademark must be proved, *Telechron, Inc.* v. *Telicon Corp.*, 97 F.Supp. 131, 151-52 (D. Del. 1951) aff'd 198 F.2d 903 (3 Cir. 1952). *Singer Manufacturing Co.* v. *June Manufacturing Co.*, 163 U.S. 169 (1896), cited as authority in this attack on the validity of CYCLOSPASMOL, is clearly distinguishable. In *Singer*, as in the *Bayer* case, *supra*, p. 29, there was proof that the purported trademark had in fact been used as, and was understood to be the name of, a certain type of machine. *Saxlehner* v. *Wagner*, 216 U.S. 375 (1910), also cited, likewise does not support defendants' claim, for in that case the name in question had significance only as a geographical expression. In the present case, there is no evidence that CYCLOSPASMOL, as opposed to the term cyclandelate, ever functioned to identify any ingredient or therapy either before or after patent expiration.[17]

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[17] Parenthetically, the evidence reinforces the legal presumption that CYCLOSPASMOL functions as a trademark. A patient in the replication survey, for example, misidentified the defendants' blue/red capsules as CYCLOSPASMOL, but added the comment "But we take the generic one and it's called Cyclandelate and dr. said it's the same and it costs a lot less". (TR 76, Pl. Ex. 78) In New York, the law requires that prescription labels showing a generic name also include the name of its source; that is not required when the trademark is used on labels, the presumption, as

The question of secondary meaning of the appearance of the Ives' capsules may be relevant to the claim under §43a of the Lanham Act, but not to the claim under §32, *Vibrant Sales, Inc.* v. *New Body Boutique, Inc.*, 211 U.S.P.Q. 297, 301 (2 Cir. 1981). The issue under §32 is not whether the appearance of the capsules is itself a trademark, or whether use of the colors on the products of defendants constitutes a false representation or a false designation of origin. The issue is whether the defendants, by furnishing the instrument making infringement possible and more likely, should be liable for the unquestioned infringement of Ives' registered trademark CYCLOSPASMOL when that trademark is used on pharmacy labels to identify the defendants' products. "Protection is accorded against unfair dealing whether there is a technical trademark or not." *William R. Warner Co.* v. *Eli Lilly Co.*, *supra*, p. 23 (265 U.S. at p. 531) Thus, an oral communication to pharmacists suggesting the passing off is actionable and will obviously be enjoined. By making the communication herein, i.e., furnishing the look-alike capsules (and further emphasizing the colors in their catalogs),[18] defendants are equally liable because of the reasonable foreseeability of the pharmacsts' misbehavior. The activity to be enjoined, i.e., the furnishing of look-alikes, is a crucial element in the behavior which leads to deception of the consumer, *Pro-Phy-Lac-Tic Brush Co.* v. *Abraham & Straus, Inc.*, 11 F.Supp. 660 (E.D.N.Y. 1935); *H. A. Metz Laboratories* v. *Blackman*, 153 Misc. 171, 179, 275 N.Y. Supp. 407 (Sup. Ct. N.Y. County 1934).

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admitted by defendant's Dr. Stempel, being that, by itself, the drug's trademark serves as an indication of source. "Obviously everyone knows [the trademark] is the ownership of the specific company . . ." (TR 784)

[18] Defendants represent that it has long been a practice for generic manufacturers to duplicate the appearance of innovator products. They have never explained why, if this is true, it was necessary for the defendants to emphasize the color identity in their promotional material.

For the same reason, cases cited by various petitioners suggesting that color per se does not function as a trademark are not relevant. Ives does not claim that it alone in the pharmaceutical industry has the right to sell drugs in blue or blue/red capsules. The relief sought and granted enjoins only the sale of *cyclandelate* in such capsules because the identity of color in that instance leads to illegal substitution, passing off, and deception.

Nor can liability be escaped merely because the physician chooses the product, but the patient purchases and consumes it, *E.R. Squibb & Sons* v. *Premo Pharmaceutical Laboratories, Inc., supra,* p. 6 n.5 (195 U.S.P.Q. at p. 549). To hold otherwise would mean that consumers of prescription drugs would have *less* protection than would consumers of ordinary products, a result directly contrary to what Ives suggests are the correct cases, holding that such consumers are entitled to even *more* protection, given the special nature of prescription drugs, *Syntex Laboratories, Inc.* v. *Norwich Pharmacal Co.*, 437 F.2d 566 (2 Cir. 1971).

II.

Enjoining the Copying of the Capsule Colors Is the Only Relief That Can Effectively Prevent Further Deception, in Support of the Policies Embodied in the Lanham Act, and Is Completely Consistent With Federal Policy Encouraging Competition and with State Substitution Laws.

A. *The Relief Granted Was Appropriate, and Necessary to Avoid Further Deception*

Judge Mansfield held that the simplest way to reduce illegal substitution and mislabeling is to require that cyclandelate be sold in capsules that do not resemble those used for CYCLOSPASMOL. This would alert patients to the possibility that they have been given cyclandelate when their doctor specifically prescribed CYCLOSPAS-

MOL, as well as put them on notice that the lower cost of generic cyclandelate should have been charged if that is what they received. (PA 86a) Although the various petitioners and amici urge that the Court should have fashioned relief that did not require color change, they do not agree on what should have been done. None of the lesser forms of relief suggested are realistic and none give adequate protection to plaintiff or the consumer.

The New York Attorney General urges that the imprinting of a symbol on the otherwise identical capsules would sufficiently disclose their source to patients. This product is taken principally by the elderly, whose eyesight may be failing, and any imprint must perforce be very small. The District Court acknowledged that, realistically, such an imprint would "be of little if any value". (PA 61a) The Court in *SK&F* v. *Premo, supra,* p. 6 n.4, also noted, after examining a small maroon and white capsule, that "to our over-fifty eyes the logos are decipherable only with great difficulty". (625 F.2d at p. 1061) Where the proposed imprint is a number, as, for example, Inwood's "258," it is evident that, even were it visible, it could not effectively serve as a distinguishing characteristic for laymen.[19]

The second remedy, suggested by Premo, is to require that a label warning them not to illegally substitute or mislabel be put on bottles sold to pharmacists. Such relief was granted in *William R. Warner & Co.* v. *Eli Lilly & Co., supra,* p. 23, where duplication of the product's brown color could not reasonably be enjoined because the color, unlike the present case, was dictated by the necessary chocolate ingredient and was thus functional. In *Upjohn Co.* v. *Schwartz,* 246 F.2d 254 (2 Cir. 1957) similar limited relief was granted for the same reason. Even in those circumstances, where the more effective relief was unavail-

[19] In the survey, patients identified even the blue and blue/red capsules imprinted with the name Premo as CYCLOSPASMOL. Capsules imprinted with the name Premo were passed off by one pharmacist as CYCLOSPASMOL. (TR 87, 726A)

able because of the nature of the particular products, the *Lilly* relief has been strongly criticized by a leading authority as granting protection that "was quite inadequate and invited the substitution which it sought to prevent," W. J. Derenberg, Trade-Mark Protection and Unfair Trading, 264 (1936). Recent cases agree that disclaimers are not a reasonably effective way of preventing confusion, even in those instances where the ultimate consumer sees the disclaimer, see e.g. *Boston Professional Hockey Association, Inc.* v. *Dallas Cap & Emblem Mfg. Inc.*, 510 F.2d 1004, 1013 (5 Cir. 1975), *cert. denied*, 423 U.S. 868 (1975). Here the customer/patient would not see the disclaimer, which would appear only on the manufacturers' bottles as sold to the pharmacist. So, once again, the responsibility for compliance would rest on the pharmacists. If they do not obey the requirements of the law, it is unrealistic to assume they would obey the manufacturers' warning label. Thus the District Court held that such statements are hardly likely to deter deliberate and fraudulent substitution. (PA 61a) This Court's comments in *Virginia State Board of Pharmacy* v. *Virginia Consumer Council, Inc.*, 425 U.S. 748, 769 (1976), apply equally here:

> "There is no claim that the advertising ban in any way prevents the cutting of corners by the pharmacist who is so inclined. *That pharmacist is likely to cut corners in any event.* The only effect the advertising ban has on him is to insulate him from price competition and to open the way for him to make a substantial, and perhaps even excessive, profit in addition to providing an inferior service." (emphasis supplied)

The Government suggests a third form of relief,[39] which has not previously been considered by any Court, or suggested by any defendant, namely to require that pharma-

[39] In an amicus brief submitted in this case on the first appeal, the Government suggested that consumer deception could be avoided by requiring an imprint on each capsule. It has apparently now retreated from that position.

cists dispense the cyclandelate capsules in the original manufacturers' bottles which identify their source. This suggestion betrays a disappointing lack of familiarity about the dispensing of drugs, and would do an economic disservice to patients. Prescriptions are tailored to a patient's individual and very different needs and are not written in predictable, standard amounts. It is doubtful that generic manufacturers could provide bottles in the very wide range of sizes necessary to accommodate these varied prescription requirements without substantial additional cost, or that pharmacies would reasonably be able to stock these many sizes. This proposal also deprives consumers of the savings that can now be realized when pharmacists purchase drugs in very large quantities, as for example, the 500 and 1,000 capsule bottles in which cyclandelate is available—a quantity far in excess of any prescription that could reasonably be written for a patient. Also, the manufacturers would, by law, be required to provide these bottles with child-proof safety closures. Since patients can request, at the pharmacy level, that some other closure be substituted, each pharmacist would have to stock closures to fit all of the manufacturers' bottles. And, it is not unlikely that, for aesthetic or other reasons, pharmacists would place their own required labels over the original label on the bottles as dispensed. The suggested relief, thus, is not only completely at odds with ingrained physician and pharmacy practice, but would increase the cost and probably decrease the availability of generic and, possibly, all drugs.

The Department of Justice has also urged that banning color copying in the institutional submarket is not necessary. The testimony, however, overwhelmingly established that the truly effective relief, a change in color, would not adversely affect that submarket at all. Institutions are required to purchase by price, not color, and often change the source, and thus the color, of medication without problems. Also, the patient's right to exercise informed

consent, which is undermined by the existence of look-alikes, is just as important to patients treated in an institution as elsewhere.[21] If effected, this relief would also require generic manufacturers to produce their products in two distinct colors, to be provided according to the type of customer ordering. The extra work, and inventory controls required, would undoubtedly also lead to increased cost.

The District Court and the Attorney General also suggest that the penalties set forth in the New York Education law provide sufficient deterrence. On the first appeal, Judge Friendly held that the fact that pharmacists may be accountable under that law does "not necessarily displace the protection for competitors embodied in trademark and unfair competition law". (PA 34a) Any other conclusion would fail adequately to protect Ives and the interests of the public. The Attorney General's own Report shows that the New York State Pharmacy Board gives low priority to the enforcement of the generic substitution law (*supra* p. 11). The record shows only a few indictments in the four year history of the law. Its existence has not had a sufficient deterrent effect in the past, and it is unrealistic to believe that it will in the future. Detection is the problem. Illegal substitution and misbranding of look-alikes goes undetected and unreported by patients who do not know that the illegality has occurred. Most cases of misconduct thus go unchallenged by the Pharmacy Board or prosecutors who, in any event, have numerous other more pressing enforcement obligations.

Defendants' trade association also asserts that the state substitution laws fully accommodate the unfair competi-

[21] The potential for patient deception and confusion exists there, as in pharmacies. Defendant's witness, Ms. Gringauz, acknowledged that, when filling prescriptions in a hospital pharmacy for a brand name drug signed "Dispense as Written", but involving Medicaid reimbursement, she disregards the physician's instructions and fills those prescriptions instead with a generic product. (247-8A, TR 717)

tion laws by requiring that pharmacists label prescriptions to show the drug's source. Not all states have such a requirement. And, even when they do, pharmacists fail to comply. For example, in Premo's pharmacy shop, 14 of 25 pharmacists in New York failed to designate the source of the drug dispensed (*supra*, p. 10).

An injunction against color copying is the only effective relief and the last clear chance to protect the patient receiving a prescription drug. As Judge Friendly noted on the first appeal, it is color that furnishes the only effective direct communication between the manufacturer and the ultimate consumer. If the color is the same, the consumer has no effective way to tell whether he or she has received CYCLOSPASMOL or some generic look-alike. The protection or self-help inherent in the sale of over-the-counter medication is not available. Defendants have cited *Norwich Pharmacal Co.* v. *Sterling Drug, Inc.*, 271 F.2d 569 (2 Cir. 1959), *cert. denied*, 362 U.S. 919 (1960), in which it was held that the defendant could sell its over-the-counter medicine for the relief of upset stomach in the same soothing pink color as plaintiff's medicine. In that case, however, the bottles in which the medicines were sold were of different shapes, the color of the labels and caps differed and the trademarks on the bottles, which could be examined before purchase, were in type large enough to be distinguished at a reading distance of over twenty feet. "It stretches credulity to imagine a purchaser confusing these disparate articles." (271 F.2d at p. 571) It does not stretch credulity to imagine one confusing one blue/red capsule with another blue/red capsule, particularly when they are mislabelled CYCLOSPASMOL.

B. *An Injunction Against Copying the Appearance of CYCLOSPASMOL Is Completely Consistent With the Federal Policy of Encouraging Lawful Competition*

Defendants submit that to require a change in the capsule colors would conflict with the federal policy allowing

the copying of products not protected by patent.[22] They also assert that their ability to compete will be inhibited because of patient resistance to, or refusal of, generic substitutes in appearances different from the innovator products. These submissions do not survive analysis and have no legal or factual support.

The cases principally relied upon to support the first claim are *Kellogg Co.* v. *National Biscuit Co.*, 305 U.S. 111 (1938) and the *Sears/Compco cases*, supra, p. 2 n.2. Under these cases the defendants have the right to sell the drug cyclandelate. Ives has never claimed otherwise. These cases do not, however, condone the sale of the drug in a form or trade dress that fosters deception. On the contrary, they clearly support the countervailing policy, as expressed in the Lanham Act, and in applicable state laws, requiring that copiers take steps to avoid such deception.

In *Kellogg*, the issue was whether a competitor could copy the pillow-shaped form for a shredded wheat cereal product. The innovator had owned a mechanical patent on a machine designed to produce only pillow-shaped biscuits and a design patent covering the pillow-shape. (pp. 119-120) Both patents expired. And, the cost of manufacture would have increased and product quality lessened were the pillow form not used. (p. 122) In the circumstances, the Court held that what was covered by the patents, i.e. a pillow-shape and a machine that was designed to produce only pillow-shaped forms, were free to copy.

However, while allowing copying, the Court also held that "fairness requires that it [the copying] be done in a manner which *reasonably distinguishes its product from*

[22] Although some defendants now argue that their right of free speech has been violated, this claim has no merit. The injunction in this case requires only that they change the color of their capsules. It does not restrict defendants from making any truthful statements they wish about their products.

that of plaintiff." (p. 120, emphasis added) It sanctioned Kellogg's copying because the company used labels with a striking difference, prominently featured its own name, and sold the product in cartons differing in size, form and color. (pp. 120-121) Even the biscuits themselves, although pillow-shaped, were otherwise different in size and appearance. (p. 121)

The *Sears/Compco* cases, *supra*, p. 2 n.2, also specifically address the matter of labelling, passing off and trade dress. The question before the Court in *Sears* was whether a "State's unfair competition law can, consistently with the federal patent laws, impose liability for or prohibit the copying of an article which is protected by neither a federal patent nor a copyright". (376 U.S. at p. 225) In that case, the respondent's design and mechanical patents on a pole lamp were held invalid. The Court held that the article was thus in the public domain and could be copied. For a state to bar copying would be an encroachment on the federal patent system. *Compco*, the companion case, involved a lighting fixture which also had been held entitled to neither a design nor a mechanical patent. The holding was essentially the same as in *Sears*.

It is no exaggeration to say that these cases have been cited in almost every unfair competition case brought since 1964 by defendants seeking to justify almost every kind of commercial chicanery involving copying. While the cases involved federal pre-emption, and did not purport to restrict the applicability of either §32 or §43a of the federal Lanham Act, the defendants here nonetheless argue that the policies expressed in *Sears/Compco* would preclude relief on those federal causes of action as well. They forget that this Court did not preclude entirely the application of even state unfair competition laws. In *Sears*, it held (p. 232):

> "Doubtless a State may, in appropriate circumstances, require that goods, whether patented or unpatented, be labeled or that other precautionary steps be taken

> to prevent customers from being misled as to the source, just as it may protect businesses in the use of their trademarks, labels, or distinctive dress in the packaging of goods so as to prevent others, by imitating such markings, from misleading purchasers as to the source of the goods."

And, in *Compco,* the Court acknowledged that a state "has power to impose liability upon those who, knowing that the public is relying upon an original manufacturer's reputation for quality and integrity, deceive the public by palming off their copies as the original." (p. 238) To that end, it may require that a copier "label or take other precautions to prevent confusion of customers as to the source of the goods". (pp. 238-39) The scope of protection available under the federal law of infringement or unfair competition as embodied in §§32 and 43a of the Lanham Act is surely at least as broad as that allowed to the states under *Sears/Compco.*

The fact that the defendants are free to sell what was covered by the now-expired patent completely protects the public interest and conforms with the policy as expressed in the *Kellogg* and *Sears/Compco* cases. This case does not involve product copying. It involves the copying of the trade dress in which a product has been sold. It has nothing to do with extending a patent monopoly. The patent did not cover, nor even mention, the particular appearance of the Ives' capsules. It covered the drug itself, which is a white powder. Upon expiration of the patent, defendants were free to sell that product in tablet form, or in capsules of any one of thousands of color combinations. The fact that the colors have nothing to do with the patent nor with the characteristics of the *product* during the life of the patent is perhaps best illustrated by the fact that Ives' did not sell cyclandelate in the blue/red capsules until three years *after* expiration of the patent. Yet defendants seek this Court's sanction to copy those

blue/red colors, as well as the blue color of the capsules in which the product was sold during the patent life.

C. *The Capsule Colors Are Not Functional, and Are Not Essential for Effective Competition*

William R. Warner & Co. v. *Eli Lilly & Co., supra,* p. 23, and such other authorities as *Smith, Kline & French Laboratories* v. *Clark & Clark,* 157 F.2d 725 (3 Cir. 1946), *cert. denied,* 329 U.S. 796 (1946), establish criteria for determining whether the appearance of medication is inherently functional. In the first-named case the Court held that the producer of a quinine preparation, colored and flavored with chocolate, could not enjoin use of the color brown for a similar quinine product. The chocolate, which made the preparation palatable and acted as a suspending medium for the quinine, served "a substantial and desirable use, which prevents it from being a mere matter of dress." (265 U.S. at p. 531) There was, the Court held, no "equally satisfactory substitute" for the chocolate, and the brown color imparted to the finished product was the natural color of this essential ingredient. In *Smith, Kline & French Laboratories* v. *Clark & Clark, ibid.,* the appearance of a pill was functional because the scoring and concave bottom allowed its separation into smaller doses; the white color was dictated by the fact that the pill was composed of white sugar-milk; the bevelled edge prevented crumbling, and the roundness of the pill made it less expensive to manufacture.

The blue and blue/red colors of the Ives' capsules are clearly not inherently functional by these standards.[23]

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[23] The National Association of Pharmaceutical Manufacturers has referred to promotional material which purports to emanate from Parke-Davis, a capsule manufacturer. It refers to the psychological effects created by certain colors as used on medication. This document was not introduced at trial, and no testimony established any relationship of the colors blue or blue/red to the therapeutic activity of a vasodilator. Likewise there was no evidence that the blue or blue/red colors had any placebo effect.

Thus, the Court held, on the first appeal, that the case for acquired functionality would depend on what defendants proved at trial.

The Court on the second appeal held that defendants failed to substantiate their excuse for copying based on acquired functionality. The defendants challenge this decision because Judge Mansfield, writing for the majority, noted that the evidence submitted by the defendants on this issue was "unconvincing" and "not persuasive", but did not use the specific words "clearly erroneous" when making holdings contrary to the District Court. This is a matter of semantics. In any event, the findings on Appeal were based not only on uncontradicted facts, but also on defendants' failure to introduce certain crucial evidence, including the testimony of patients, a survey of patient attitudes toward color change, and evidence that color change causes confusion.[24] The Department of Justice has characterized defendants' evidence on functionality as "sparse." (Amicus Br. p. 30) Defendants in other cases have offered not only similar excuses for copying, but, in some instances, even the same witnesses, and the excuses have likewise been rejected, in one instance as "utterly specious," *Boehringer* v. *Pharmadyne, supra,* p. 8 n.8. (211 U.S.P.Q. at p. 1173) Also the error in the District Court's opinion was not only in making findings of fact with no reasonable basis in the record, but also in applying legal standards incorrectly.

The mere fact that some features of a product's appearance may have an incidental use does not and should not mean that it thereby satisfies the legal standard of functionality and may be freely copied, *Time Mechanisms, Inc.* v. *Qonaar Corp.*, 422 F.Supp. 905, 914 (D.N.J. 1976); *Le Sportsac, Inc.* v. *Dockside Research, Inc.*, 478 F.Supp. 602,

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[24] The District Court made no finding of credibility as to any witness. There is not, as suggested by the Department of Justice, a sharp conflict in the evidence submitted on functionality. The Court of Appeals decision was correct even if only the defendants' evidence is considered.

607 (S.D.N.Y. 1979); *Rolls-Royce Motors Ltd.* v. *A. & A. Fiberglass, Inc.*, 428 F.Supp. 689, 692 (N.D. Ga. 1976); *Dallas Cowboy Cheerleaders, Inc.* v. *Pussycat Cinema, Ltd.*, 604 F.2d 200, 203 (2 Cir. 1979):

> "We do not quarrel with defendants' assertion that a purely functional item may not become a trademark . . . However, we do not agree that all of the characteristics of plaintiff's uniform serve only a functional purpose or that, because an item is in part incidentally functional, it is necessarily precluded from being designated as a trademark . . . the feature may become a trademark even though it serves a useful purpose."

Copying of the appearance of a prescription drug likewise is not condoned merely because the color may have some incidental use, or that the shape may serve some incidental useful purpose, *A.H. Robins* v. *Medicine Chest, supra*, p. 7 n.8; see also *Ross-Whitney Corp.* v. *Smith Kline & French Laboratories, supra*, p. 7 n.7.

The basis for defendant's claim of function, and their excuse for exactly copying the appearance of CYCLOSPASMOL capsules comes down to this: patients believe the colors signify therapy and will refuse color change; pharmacists thus will not stock, hospitals will not dispense, and physicians will not prescribe drugs that do not copy the market leader. No patient, however, testified that color signifies therapy. The overwhelming evidence is that any patient inquiry about a color change can be explained satisfactorily by a pharmacist or physician; physicians prescribe regardless of color; pharmacists stock the same drugs in many different colors; hospitals and other institutions buy, and indeed are required to buy, by price, without regard to color; purchasing specifications on the federal, state, and local level throughout the country contain no reference to color, with one exception. (*supra*, pp. 14, 15) Use of color as the means of identification in the emergency room is dangerous, particularly since products with

very different therapeutic ingredients may have a similar appearance. For the same reason the commingling of drugs by patients, and the selection of one or the other thereafter by color is universally condemned. (*supra*, pp. 13-14)

Of the numerous recent cases that have involved this functionality issue, it is only the District Court in this action that accepted the defendants' excuses, without the benefit of any patient's testimony—although the entire basis of the argument is a claimed therapeutic significance of the color to the patient.[25] The majority of the Court of Appeals correctly rejected defendants' unproved claim, as have other courts. *SK&F* v. *Premo, supra*, p. 6 n.4; *A. H. Robins* v. *Medicine Chest, supra*, p. 7 n.8; *Boehringer* v. *Pharmadyne, supra*, p. 8 n.8; *Marion Laboratories, Inc.* v. *Michigan Pharmacal Co.*, 338 F.Supp. 762 (E.D. Mich. 1972) aff'd without opinion 473 F.2d 910 (6 Cir. 1973).

There is, however, another string to defendants' bow. It is easier to compete, they say, if they can duplicate the appearance of the blue and blue/red trade dress. This expansive interpretation of functionality has its apparent basis in cases such as *Pagliero* v. *Wallace China Co.*, 198 F.2d 339 (9 Cir. 1952) in which it was held that the ornamental patterns on china could be copied because "the particular feature is an important ingredient in the commercial success of the product". (p. 343) To require, under this standard, that defendants need prove only that they can sell more by copying than not copying goes far beyond any reasonable test of functionality and in fact would permit all acts of unfair competition or infringement merely because those acts increase sales. As the Court in *SK&F* v. *Premo, supra*, p. 6 n.4, observed of Premo's claim that

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[25] In support of its functionality claim, Inwood relies on material appearing in the supplement to a legal treatise, Callman, The Law of Unfair Competition Trademarks and Monopolies (3rd Ed. 1970). The author of the comments cited is Seymour Kleinman, a member of a law firm that has represented generic drug companies who are also defendants in many of the recent look-alike cases.

copying color made competition easier, "probably it could compete better still if it could appropriate the same trade name. But neither appropriation has the look, sound or feel of equity". (625 F.2d at p. 1067)

Of particular relevance is the undisputed evidence of widespread use of different colors for the same dosage form of the same medication by different manufacturers. There is no evidence that their sales have suffered because they do not copy. And, there is no reason why, in the case of cyclandelate, uniformity of color should be expected by physicians, pharmacists and patients, when they do not encounter this phenomenon generally. There certainly is nothing inherent about the fact that this product is a vasodilator. The most widely prescribed vasodilator is available in the same dosage form from different sources in many different colors. Cyclandelate itself is sold by one competitor in an all-red capsule. (*supra*, p. 12)

Defendants, however, have claimed that companies that copy the innovators' products, but not their appearance, market their products differently, by utilizing detail men and advertising. The record does not support this blanket conclusion. (307-8A, 314A) SK & F, for example, has sold a full generic line for several years without duplicating the distinctive appearance of the pioneer drugs, and the testimony was that this line is not detailed. (305-6A, 314A) Even if taken at face value, however, the defendants' argument completely undercuts defendants' claim of functionality, which rests completely on the alleged significance of color to patients. All else follows. To accept defendants' "explanation" about the numerous non-look-alikes on the market, which they claim are sold in a manner different from defendants' products, one must conclude that whether the color means therapy to patients and leads to their acceptance or rejection of a different colored substitute depends on who later copies that drug, defendants or a company using detail men or advertising, although the patient has no way of knowing

how the drug has been promoted. Color change, under defendants' theory, is rejected by the patient if defendants manufacture the drug; it is accepted if a company in the other category manufactures it![36] And, if color indeed signifies therapy or the active ingredient, and availability of more than one color causes concern, how then can Premo explain its copying of *both* colors of two market leaders selling the *same* medication in tablets, one yellow and one peach. (258-9A)

It is also significant that defendant Premo has changed the colors of medication as the result of other litigation, and then merely noted in its price sheets that the colors were new. (607A) Yet no one offered proof at trial that these color changes in any way adversely affected the sale of these products.

Individual manufacturers of cyclandelate, all of whom are enjoined from copying, will not be at a competitive disadvantage.[37] Institutions and pharmacies will continue as they now do, to stock generic drugs whatever their colors. These manufacturers remain free to compete with one another, and with Ives, on the basis of price and quality.

D. *The Relief Granted Is Consistent With and Supports Public Policy; to Deny Such Relief Undermines That Policy*

There is a policy in favor of allowing copying of a product after the patent expires. There is likewise a policy in

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[36] The fact that the non-look-alike product may be sold under a trademark does not affect its availability for substitution. The testimony showed that, under New York law, the less expensive equivalent is to be dispensed, whether or not it bears a brand name. (TR 791-2)

[37] In an interview reported in the October 19, 1981 issue of The Record (Bergen County, New Jersey), Mr. Blackman, president of Premo, is quoted as saying "I would personally not mind if the Supreme Court upheld the decision of the circuit courts. The benefits of being able to hold products to yourself by controlling color is an advantage to major manufacturing and generic companies. It could make our industry more profitable."

various states fostering the availability of generic drugs. The relief granted in this case is consistent with both policies. Cyclandelate will still be freely available, but defendants will have to compete fairly, as does W. E. Hauck Co., by selling cyclandelate in capsules that are not the colors of Ives' capsules.

The inevitable result of allowing the continued sale of look-alike drug products is to keep patients in ignorance of the fact that they are receiving a product different in source and price from that previously dispensed. Patient ignorance, in fact, is exactly what defendants espouse, for they argue strenuously that patients are reluctant to accept change, and that a different color might alert them to the fact that there has been a change. Concealing this is, however, completely inconsistent with the policies of the state substitution laws,[28] and with public policy generally. It negates a patient's right to exercise informed consent as to the medication dispensed to him or her.

In *Virginia State Board of Pharmacy* v. *Virginia Citizens Consumer Council, Inc., supra,* p. 34, this Court recognized the importance of patient access to information about the pricing of drug products. The Court's reasoning applies with equal force to this situation in which patients are being kept in ignorance of perhaps an even more important aspect of health care, namely the true source of their medication (425 U.S. at p. 770):

> "There is, of course an alternative to this highly paternalistic approach. That alternative is to assume that this information is not in itself harmful, that people will perceive their own best interests if only they are well enough informed, and that the best means to that end is to open the channels of communication rather than to close them."

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[28] Respondent, in any event, questions whether issues of state public policy raised by Petitioners and amici are relevant in determining whether a cause of action under federal law has been established.

The concealment of change resulting from the dispensing of look-alikes also violates the policy of the State of New York,[39] as expressed in *Pharmaceutical Society of the State of New York* v. *Lefkowitz*, 586 F.2d 953 (2 Cir. 1978). The purpose of the New York substitution law is to permit prescriptions to be filled with less expensive equivalent drug products when a physician is willing to permit use of the substitute. The law was not intended to interfere with a patient's informed choice of medication (586 F.2d at p. 958):

> "The decision to use a brand name or generic drug and which brand name to use, remains as before with the doctor and the patient; the provisions of the Generic Drug Act only come into play *after* their initial choice (usually that of the doctor) has been made between 'dispense as written' and 'substitution permissible'. Here, as under prior law, there is no deprivation of the right of the patient, with the advice of his or her doctor, to decide on the proper medication."

That choice is negated in instances of undetected illegal substitution. And, the aim of lowering drug costs is thwarted where a generic is substituted, as authorized, but an adequate cost saving is not forthcoming, and the patient is not alerted to inquire. There is no generic substitution law requiring that the fact of substitution be concealed from the patient, which is the aim of defendants' practices; on the contrary all require, in one form or another, that the patient be informed.

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[39] Attorney General Abrams' assertion that New York State public policy favors the availability of generic drugs in look-alike colors lacks credence. Neither the New York generic substitution law, nor any other law, makes such a requirement. Also, the Attorney General's statement is inconsistent with the purchasing practices of state institutions, none of which require color in their bidding specifications, supra p. 15. The conclusions in his brief assume the validity of defendants' claim that patients will not accept color change in their medication, whereas the record herein shows that this is not so.

The sale of these drugs in look-alike capsules also allows a manufacturer to avoid accountability for the quality of its products. It exposes Ives to the risk of physician or patient dissatisfaction with the look-alike capsules, particularly those which have been dispensed and labeled with Ives' trademark, and to the further risk of suit,[30] against it, "the deep pocket defendant," *SK & F* v. *Premo, supra,* p. 6 n.4 (625 F.2d at p. 1066). This concern applies whether or not proof has been offered as to the present equivalence or nonequivalence of the drugs, *Hoffman LaRoche* v. *Premo, supra,* p. 6 n.4 (210 U.S.P.Q. at p. 382). It is well established that a manufacturer should not be forced to place its reputation in the hands of another over whom he has no control, *Yale Electric Corp.* v. *Robertson,* 26 F.2d 972 (2 Cir. 1928).

III.

Ives Has Also Established a Right to Relief Under §43a of the Lanham Act and the New York State Law of Unfair Competition.

This case is in an unusual posture. Ives claimed that defendants were liable on three causes of action. The Court of Appeals decided only the contributory infringement claim. The Department of Justice in its Brief Amicus suggests that the Court should instead have decided the § 43a claim, and asks that this Court remand this case for consideration of that claim, with guidelines setting forth the scope of liability under §43a.[31] Ives submits that the finding

[30] Although Ives did not submit evidence as to equivalence, it should not have to risk its reputation on the future quality of the look-alikes. An FDA inspection in 1978 showed, for example, that Inwood had significant deviations from good manufacturing practice, indicating a lack of control over manufacturing, testing and release of drug products. (FDA Establishment Inspections, 6/19-23, 26-30; 7/5-7, 18-21, 26-28, 31 and 8/1-4, 7 and 8, 1978) In 1981, Inwood manufactured cyclandelate capsules that failed weight variation tests. (FDA Establishment Inspections, Sept. 3, 4, 8 & 11, 1981).

[31] The Department of Justice also asks this Court to hold that defendants are not liable for damages or an accounting of profits.

of contributory infringement is completely justified. However, it is equally clear that Ives also proved its case under §43a.[12]

The Court on the first appeal held that defendants would be liable under §43a if Ives proved that the capsule colors had acquired secondary meaning, and if they were not functional. The functionality issue has already been addressed by the Court of Appeals, which held that the proofs offered by the defendants to justify copying—which were based on the alleged functionality of the capsule appearance—were "unconvincing" and "not persuasive." Ives also clearly proved secondary meaning. The capsule colors were completely arbitrary when selected, with no relationship to the ingredients or therapy of the product. There were extensive sales of CYCLOSPASMOL cyclandelate in blue and blue/red capsules, and starter samples showing the trademark CYCLOSPASMOL and identifying Ives as their source were distributed to patients. The colors, with the trademark and the Ives name, were depicted both in a widely used medical reference book and a Guide to prescription drugs for laymen. (*supra*, p. 5)

Perhaps the best proof that the colors had come to signify CYCLOSPASMOL capsules, however, is the fact that

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This issue is completely premature. On remand, the District Court held that plaintiff was entitled to damages and an accounting, but stayed the proceeding which will determine the extent of that liability pending the outcome of this appeal. The Court of Appeals itself never considered the question of damages and an accounting, and presumably cannot do so until the appeal, if any, from the final decision of the District Court after a hearing on that issue. In any event, particularly given the specific finding of intent on the part of defendants, such an award would certainly be justified.

[12] Since the Court of Appeals has not decided the claim, it is technically not before this Court and an extended discussion of the §43a theory of liability does not appear to be appropriate. However, should the Court decide to consider the §43a claim, despite the fact that the Court below did not do so, Ives seeks permission to submit a supplemental brief on that issue.

the defendants deliberately copied those colors. Were they not associated with CYCLOSPASMOL, there would have been no reason for them to do so. The excuses offered by defendants to justify the copying were rejected by the Court of Appeals. In the circumstances, secondary meaning had been clearly proved by the same kinds of evidence correctly accepted in *SK&F* v. *Premo, supra,* p. 6 n.4; *A.H. Robins* v. *Medicine Chest, supra,* p. 7 n.8; and *Boehringer* v. *Pharmadyne, supra,* p. 8 n.8.

Although the Department of Justice asserts that the Ives survey of physicians and patients was the sole evidence of secondary meaning submitted, in fact the survey merely corroborated what the other evidence, as aforesaid, had already established. Specifically it established that, when shown blue and blue/red capsules, physicians and patients will misidentify those capsules as CYCLOSPASMOL because of the color.

Ives' third cause of action was based on state unfair competition law. Under New York law, which applies in this case, the deliberate copying of arbitrary trade dress will be enjoined without independent evidence of secondary meaning, *Perfect Fit Industries, Inc.* v. *Acme Quilting Co., Inc.,* 618 F.2d 950, 953-4 (2 Cir. 1980):

> ". . . monopolization is not a problem in the realm of trade dress, because the possible varieties of advertising display and packaging are virtually endless. Thus, in this area New York law has concerned itself principally with whether or not the public is likely to be confused, rather than with whether the first comer's trade dress has acquired secondary meaning.
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> • • •
>
> "If there was intentional copying the second comer will be presumed to have intended to create a confusing similarity of appearance and will be presumed to have succeeded."

Ives submits that it established liability under this cause of action as well. Public policy would not bar the relief. On the contrary, to allow the continued sale of look-alikes, and thereby conceal the fact that a generic masquerading as the innovator has been dispensed, would undermine the policy of the state substitution law, as aforesaid. Should this Court remand the case to the Court of Appeals for consideration of the §43a claim, respondent asks that the remand include a direction to determine the New York claim as well.

CONCLUSION

Respondent, Ives Laboratories, Inc., submits that the decision of the Court of Appeals was in all respects correct, and should be affirmed.

Respectfully submitted,

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Nos. 80-2182 and 81-11

IN THE

SUPREME COURT OF THE UNITED STATES

OCTOBER TERM, 1981

INWOOD LABORATORIES, INC., *et al.*,

Petitioners,

v.

IVES LABORATORIES, INC.,

Respondent.

DARBY DRUG CO., INC., *et al.*,

Petitioners,

v.

IVES LABORATORIES, INC.,

Respondent.

Certificate of Service

I hereby certify that on this day of January, 1982, three copies of the within Respondent's Brief with revised record references were served by first class mail postpaid on each of the following: Bass, Ullman & Lustigman, Attorneys for Petitioner Inwood Laboratories, Inc., 747 Third Avenue, New York, New York 10017; Kirschstein, Kirschstein, Ottinger & Cobrin, Attorneys for Petitioner Premo Pharmaceutical Laboratories, Inc., 666 Fifth Avenue, New York, New York 10103; and Salon, Marrow & Dyckman, Attorneys for Petitioners Darby Drug Co., Inc., MD Pharmaceutical Company, Inc., Rugby Laboratories, Inc. and Sherry Pharmaceutical Co., Inc., 41 East 42nd Street, New York, New York 10017. I further certify that all parties required to be served have been served.

/s/ MARIE V. DRISCOLL
Marie V. Driscoll